Docket Number: IDP-1003 App. Ser. No. 10/052,528 Reply to Office action of February 22, 2007

IN THE CLAIMS

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- 1. (Original) A needle point guard safety cap assembly for securely covering and protecting the needle point of a syringe after the syringe has been used, comprising:
- a) a syringe attachment member operable to firmly attach the needle point guard safety cap assembly to the needle hub of a syringe;
- b) a needle point cover member in the form of an elongated hollow member that is open at one end for receiving the needle therein, and at its other end is mostly enclosed by an end wall having a hole through which the needle can pass;
- c) a lid adapted to close the otherwise open end of the cover member, the lid also having a hole through which the needle may pass so that the needle may extend through both holes;
- d) an extensible frame having a proximal end and a distal end, the proximal end coupled to the syringe attachment member and the distal end coupled to the needle point cover; the extensible frame being manually actuable for advancing the cover member along the needle to where the end wall of the cover member is beyond the extremity of the needle point;
- e) the needle point cover member then being supported by the hole in the lid and then, in response to further advancement of the cover member, rotating about the lid hole until the needle point passes inside the enclosed end wall of the cover member into a protected position where it cannot pass through the cover member hole.
- 2. (Original) A needle point guard safety cap assembly as in claim 1 wherein the lid is pivotally secured to the cover member; and the syringe attachment member, cover member, lid, and extensible frame are integrally formed of plastic material.
- 3. (Original) A needle point guard safety cap assembly as in claim 1, wherein the cover member further comprises a well chamber formed in the end wall adjacent to the hole for passage of the needle therein, the well chamber being operable for enclosing the sharp end of the needle once the needle point cover has be actuated, thereby preventing the sharp end of the needle from re-emerging through the hole.

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- 4. (Original) A needle point guard safety cap assembly as in claim 3 further comprising a fulcrum on the needle point cover, with the extensible frame being further operable to act on the fulcrum when the end wall of the cover member is beyond the extremity of the needle point and thereby cause the cover member to rotate such that the sharp end of the needle enters the well chamber.
- 5. (Original) A needle point guard safety cap assembly as in claim 1, wherein the extensible frame further comprises a proximal frame segment and a distal frame segment, the frame segments coupled in the center of the extensible frame with a hinge, the hinge being in a closed position prior to actuation of the needle point cover with the proximal and distal frame segments lying substantially parallel to one another, with extension of the frame being acheived by opening the hinge.
- 6. (Original) A needle point guard safety cap assembly as in claim 5, further comprising at least one securing clip on the extensible frame, the securing clip being operable to irreversibly engage the needle when the needle point cover is fully actuated.
 - 7. (Original) A needle point guard safety cap assembly as in claim 1, further comprising interlocking members on the syringe attachment member and the extensible frame, the interlocking members releasably securing the needle point guard safety cap assembly in its unactuated state and providing a tactile indication when the needle point guard safety cap assembly is actuated.
- 8. (Original) A needle point guard safety cap assembly as in claim 7, wherein the interlocking member on the syringe attachment member comprises a protrusion having a bulbous enlarged end, and the interlocking member on the extensible frame comprises a slot of a width slightly less than the diameter of the bulbous end; the protrusion and slot being positioned on the syringe attachment member and extensible frame, respectively, such that when the needle point guard safety cap assembly is in its unactuated state with the needle point cover member most distal from the needle point the protrusion engages the slot with the bulbous end of the protrusion

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passing through the slot, whereby the needle shield is releasably maintained in its unactuated state.

- (Original) A needle point guard safety cap assembly as in claim 1, wherein the sy ringe attachment member further comprises at least one annular slot to engage a corresponding annular ring on the needle hub of a syringe.
 - 10. (Original) A needle point guard safety cap assembly as in claim 1, wherein the syringe attachment member further comprises at least one longitudinal slot to engage a corresponding longitudinal ridge on the needle hub of a syringe to maintain a fixed radial orientation of the needle point guard safety cap with respect to the cannula opening of the syringe.
 - 11. (Original) A needle point guard safety cap assembly as in claim 1, wherein the needle point cover member is adapted to receive a needle sheath, thereby allowing the needle sheath to cover the needle when the needle point cover member is distal from the needle point.
 - 12. (Original) In a needle point guard safety cap assembly having (1) a syringe attachment member operable to connect the needle point guard safety cap assembly to the needle hub of a syringe; (2) a needle point cover operable to enclose the needle tip when the needle point guard safety cap is actuated; and (3) an extensible frame having proximal and distal ends, the proximal end coupled to the syringe attachment member and the distal end coupled to the needle point cover,

interlocking members on the syringe attachment member and extensible frame operable to releasably lock the needle point guard safety cap assembly in an unactuated state and to provide tactile feedback to the user when the needle point guard safety cap assembly actuation is initiated.

13. (Cancelled)

14. (Original) In a needle point guard safety cap assembly having (1) a syringe attachment member operable to connect the needle point guard safety cap assembly to the needle

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hub of a syringe; (2) a needle point cover operable to enclose the needle tip when the needle point guard safety cap is actuated; and (3)an extensible frame having proximal and distal ends, the proximal end coupled to the syringe attachment member and the distal end coupled to the needle point cover:

- (a) an inner chamber within the needle point cover operable to contain the needle tip when the needle point guard safety cap assembly is actuated, and a needle entry hole and needle exit hole in communication with the inner chamber, the syringe needle passing through the entry hole, inner chamber, and exit hole prior to actuation of the needle point cover, and then withdrawing from the exit hole upon actuation such that the needle tip is within the inner chamber;
- (b) a fulcrum integral with the needle point cover and which upon actuation of the needle point guard safety cap assembly contacts the shaft of the needle, the fulcrum operable to cause the needle point cover to rotate with respect to the needle shaft;
- (c) a lever arm also integral with the needle point cover, the lever arm operable to apply rotational force to the needle point cover; and
- (d) a pressure platform integral with the extensible frame, the pressure platform operable to apply pressure to the lever arm when the needle point guard safety cap assembly is actuated and the syringe needle tip is within the inner chamber, causing the needle point cover to rotate such that needle tip cannot re-emerge from needle point cover through the exit hole.
- 15. (Original) A needle point guard safety cap assembly for securely covering and protecting the needle point of a syringe after the syringe has been used, comprising:
 - a) means for firmly attaching the needle point guard safety cap assembly to the needle hub of a syringe;
 - b) a needle point cover in the form of an elongated hollow member that is open at one end for receiving the needle therein, and at its other end is mostly enclosed by an end wall having a hole through which the needle can pass;
 - c) means for enclosing the otherwise open end of the cover member, but permitting a needle to pass through;
- d) frame means coupled to the syringe attachment means and the distal the needle point cover means; the frame means being manually actuable for advancing the cover member along

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the needle to where the end wall of the cover member is beyond the extremity of the needle point;

- e) the cover member then being supported by the hole in the lid and, as it advances, rotating about the lid hole until the needle point passes inside the enclosed end wall of the cover member into a protected position where it cannot pass through the cover member hole;
 - f) the needle point guard safety cap assembly being integrally formed.
- 16. (Original) A needle point guard safety cap assembly as in claim 15 further comprising manually actuated locking means for securing the cover member in the needle-protective position.
 - 17. (Original) A needle point guard safety cap assembly as in claim 15 further comprising a means for releasably locking the cover in a position distal from the point.
- 18. (Original) A needle point guard safety cap assembly comprising:
 - a) a base cup comprising;
 - (i) a circumferential wall with a bottom wall attached thereto for defining a cup,
 - (ii) the cup being adapted to attach to a syringe,
 - (iii) the bottom wall of the cup having a hole therethrough to allow passage of a needle,
 - (iv) a pair of attachment arms extending outward from the circumferential wall near the base cup bottom wall, and
 - (v) a locking protrusion extending from the circumferential wall near the base cup bottom wall;
 - b) a collapsible segmented extension having at least two segments comprising:
 - (i) a wishbone segment having two arms and a base, the arms being flexibly attached to the base cup attachment arms such that the base cup can rotate about the axis formed by the attachment arms to wishbone connection; and
 - (ii) a lower segment having upper and lower ends, the upper end being flexibly attached to the wishbone base, the lower segment having a locking slot near the lower end for releasably locking the lower segment to the base cup

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locking protrusion when the segmented extension is collapsed and the lower segment is in a position adjacent the base cup; and

- c) a needle point cap flexibly connected to lower end of the lower segment, the needle point cap comprising:
 - (i) a circumferential wall, a top wall, and a bottom wall which define a chamber; and
 - (ii) the top wall and the bottom wall of the needle point cap each containing a bore therethrough to allow passage of the needle.
- 19. (Original) In a needle point guard safety cap assembly having a syringe attachment member and an extensible frame coupled to the syringe attachment member, a needle point cover coupled to the extensible frame, the needle point cover having the form of an elongated hollow member having a first end and a second end;

a lid member coupled to the needle point cover and closing the first end, the lid member having a hole formed therein for receiving the needle;

the needle point cover second end being mostly enclosed by an end wall having a hole through which the needle can be extended for use, the end wall further having a well chamber to engage and retain the sharp end of the needle when the needle is retracted.

- 20. (Original) The needle point cover of claim 19, further comprising a fulcrum member which may be acted upon by the extensible frame of the needle point safety cap assembly when the end wall of the cover member is beyond the extremity of the needle point, thereby causing the cover member to rotate such that the sharp end of the needle enters the well.
- 21. (Original) The need point guard safety cap assembly of claim 12, further comprising at least one securing clip on the extensible frame to engage the needle shaft upon activation of the needle point guard safety cap assembly to prevent the needle tip from exiting the needle point cover, the interlocking members and securing clip further serving to provide tactile feedback to the user when the needle point guard safety cap assembly actuation is initiated and completed, respectively.

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22. (Previously Presented) In a needle point guard safety cap assembly having (1) a syringe attachment member operable to connect the needle point guard safety cap assembly to the needle hub of a syringe: (2) a needle point cover operable to enclose the needle tip when the needle point guard safety cap is actuated; and (3) an extensible frame having proximal and distal ends, the proximal end coupled to the syringe attachment member and the distal end coupled to the needle point cover,

at least one securing clip on the extensible frame to engage the needle shaft upon activation of the •needle point guard safety cap assembly to prevent the needle tip from exiting the needle point c over and to provide tactile feedback to the user when the needle point guard safety cap assembly actuation is completed;

the needle point guard safety cap assembly further comprising interlocking members on the syringe attachment member and extensible frame operable to releasably lock the needle point guard safety cap assembly in an unactuated state, the interlocking members and securing clip further serving to provide tactile feedback to the user when the needle point guard safety cap assembly actuation is initiated and completed, respectively.

- 23. (Amended) A needle point guard assembly attachable to a base of a syringe having a needle to allow said needle initially to protrude into an operative position for use, said assembly also being extensible into a locked position in which the needle point is fully protected, comprising:
 - (a) a syringe attachment member operable to attach the said needle point guard assembly to the needle hub of a syringe;
- (b) an extensible frame having a proximal end segment hingedly secured to said syringe attachment member and a distal end segment hingedly connected to said proximal end segment;
 - (c) an elongate needle point cover member being open at one end, and the opposite end thereof having an end wall with a hole through which the needle when operative will extend, said end wall also having a needle point receiving well that is laterally displaced from said hole;
 - (d) said cover member at said open end, and on one side thereof, being hingedly secured to the distal end of said distal end segment;

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- (e) a lid member hingedly secured to said open end of said cover member and having a hole through which the needle may pass, but normally closing said open end of said cover member, but wherein the needle may pass through both the hole in the end wall and the hole in the lid member when extended for use;
- (f) said extensible frame being manually actuable by a single [hand] <u>finger</u> of an operator so as to be extended sufficiently to pass through the hole in the lid member, remaining within the cover member, but not protruding through the hole in the cover member;
- (g) the cover member and hinged attachment to said extensible frame being integrally formed of a plastic material such that when the distal end of the needle no longer protrudes through the cover member hole, a rotational movement of said hinged attachment causing the needle point to move laterally into the cover member well.
- 24. (Previously Presented) A needle point guard assembly as in claim 23 wherein said well in said end wall of said cover member lies in that side of said cover member that is opposite to the hinged connection of the cover member to said extensible frame.
- 25. (Previously Presented) A needle point guard assembly as in claim 23 wherein the entirety of said needle point guard assembly is integrally formed of a plastic material.
- 26. (Previously Presented) A needle point guard assembly as in claim 23 further comprising a fulcrum on said needle point cover, said extensible frame being further operable when said end wall of said cover member lies beyond the extremity of the needle point to act on said fulcrum and thereby cause said cover member to rotate such that the sharp end of the needle enters into said cover member well.
 - 27. (Previously Presented) A needle point guard assembly as in claim 23 wherein the proximal end of said extensible frame comprises a base cup for attachment to a syringe and a wishbone segment having two arms and a base, said arms being flexibly attached to said base cup such that said base cup can rotate about the axis formed by the attachment of said arms to said wishbone connection.

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28-33. (Cancelled)

34. (Amended) A protective cover assembly for a hypodermic needle having a needle base, a needle shaft, and a needle tip, the protective assembly comprising:

an elongated needle tip cover having an end wall with an opening through and beyond which the needle shaft can extend, either when the hypodermic needle is being stored prior to use or when the needle tip is exposed for use and the needle tip cover has therefore assumed a retracted position;

a collapsible frame coupled between the needle base and the needle tip cover to allow the needle tip cover to assume its retracted position, the frame also being extendible after the needle has been used to slide the needle tip cover along the needle until it protrudes beyond the needle tip;

means responsive to the extension of the frame for [twisting] <u>rotating</u> the needle tip cover into a position in which the needle tip is protected by the end wall of the needle tip cover but is precluded from re-emerging through the opening therein; and

means responsive to the extension of the frame not only for locking the needle tip cover in the needle-protective position but also for locking the frame in its thus extended position.

- 35. (Previously Presented) A protective cover assembly as in Claim 34 which includes manual contact means associated with the frame for squeezing the frame in a direction generally perpendicular to the needle to extend the frame and accomplish the needle tip protection.
- 36. (Previously Presented) A protective cover assembly as in Claim 34 wherein the needle point shield comprises an elongated hollow member having two end walls with aligned openings through which a needle can extend when in an operative position; one of the end walls also having on its interior surface a well that is laterally displaced from the associated opening, and an interior ridge between the well and the end wall opening such that when the needle after its use is retracted through that end wall opening into the interior of the hollow member the tip of the retracted needle may then be securely retained within the well and thus protected from reemerging outwardly through that end wall opening.

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37. (Previously Presented) A protective cover assembly as in Claim 36 wherein both the end wall opening of the shield and its internal ridge are laterally displaced from the center of the end wall.

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- 38. (Previously Presented) A needle shield as in Claim 36 wherein the hollow member has a circumferentially continuous side wall, characterized in that the member is formed as a unitary molded plastic piece, and has a lid to form the other end wall thereof which is pivotable into an operative position and then comes into cork-like engagement with the side wall of the member.
- 39. (Previously Presented) A needle shield as in Claim 38 wherein the outer portion of the opening in the lid is flared outwardly to facilitate the twisting of the shield relative to the needle.

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40-47. (Cancelled)

48. (Previously Presented) A needle point shield integrally formed as a single plastic piece. comprising:

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an elongated hollow member having two end walls with aligned openings through which a needle can extend when in an operative position:

a forward one of the end walls also having on its interior surface a well that is laterally displaced from the associated opening, and an interior ridge between the well and the end wall opening such that when the needle after its use is retracted through that end wall opening into the interior of the hollow member the tip of the retracted needle may then be securely retained within the well and thus protected from re-emerging outwardly through the end wall opening;

wherein the opening in the rearward one of the end walls provides a pivot support to permit the shield to twist relative to the needle passing through it. so that the needle tip then moves laterally from the opening in the forward end wall into the laterally displaced well: and

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wherein the hollow member has a circumferentially continuous side wall, characterized in that the member is formed as a unitary molded plastic piece, and the rearward end wall thereof is

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formed as a lid pivotable into its operative position and then comes into cork-like engagement with the side wall of the member.

- 49. (Previously Presented) A needle shield as in Claim 48 which further includes a
 lever arm projecting from the other end of the member and laterally displaced from its associated opening to facilitate applying a twisting force to the needle.
 - 50. (Previously Presented) A needle shield as in Claim 49 wherein the lever arm is on the side of the member that is opposite the well in the forward end wall.
- 51. (Cancelled)

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- 52. (Cancelled)
- 15 53. (Previously Presented) A needle point shield comprising an elongated hollow member having on one end thereof an end wall in which there is an opening through which a needle tip can pass; a lid hingedly supported from the other end of the hollow member and adapted to close the other end of the hollow member, the lid having a hole through which the needle can also pass; and the one end wall also having on its interior side a well that is laterally displaced from the opening and an interior ridge between the opening and the well such that when a needle has first been extended through both the hole in the lid and the opening in the end wall for purpose of its use and is then retracted, the tip of the retracted needle can be securely retained within the well and thus protected from again

re-emerging outwardly through the one end wall opening; the needle point shield being formed as a unitary molded plastic piece.

- 54. (Previously Presented) A needle point shield as in Claim 53 wherein the other end wall thereof is formed as a lid pivotable into its operative position.
- 55. (Previously Presented) A needle point shield comprising an elongated hollow member having two end walls with aligned openings, one of the end walls also having on its in-

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terior surface a well that is laterally displaced from the associated opening, the other end wall having a lever arm projecting outwardly therefrom but laterally displaced from its associated opening; whereby when the needle has been extended in an operative position through both openings and beyond the one end wall and is then partially retracted into the hollow member, force may be applied to the lever arm on the other end wall relative to its associated opening so as to cause the shield to twist about the needle at that associated opening and the needle tip to then become lodged within the well in a protected position.

- 56. (Previously Presented) A needle shield as in Claim 55 further characterized in that the member is formed as a unitary molded plastic piece, and the other end wall thereof is formed as a lid pivotable into its operative position.
 - 57. (Previously Presented) A needle shield as in Claim 55 which further includes an interior ridge between the well and the end wall opening such that when the needle after its use is retracted through that end wall opening into the interior of the hollow member the tip of the retracted needle may then be securely retained within the well and thus protected from again reemerging outwardly through the end wall opening.
 - 58. (Previously Presented) A needle shield as in Claim 57 further characterized in that the member is formed as a unitary molded plastic piece, and the other end wall thereof is formed as a lid pivotable into its operative position.
 - 59. (Previously Presented) A needle shield as in Claim 58 wherein the hollow member has a circumferentially continuous side wall, and the other engagement and the other end wall thereof when its operative position is in cork-like engagement with the side wall of the member.
 - 60. (Previously Presented) A needle shield as in Claim 57 wherein the outer end portion of the opening in the other end wall thereof is flared outwardly so as to permit the shield to twist about that opening, relative to the needle passing through it.

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61. (Cancelled)